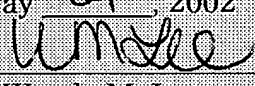




Patent Docket P0998D1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of  Jeffrey L. Cleland et al.  Serial No.: 09/273,230  Filed: March 18, 1999  For: PROTEIN FORMULATION	Group Art Unit: 1642  Examiner: G. Bansal  <b>CERTIFICATE OF MAILING</b> I hereby certify that this correspondence is being deposited with the "Express Mail Post Office to Addressee" service under 37 CFR 1.10 and is addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231 on  Express Mail Label No. : EV 016 026 819 US  May 21, 2002  Wendy M. Lee
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INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner of Patents  
Washington, D.C. 20231

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

- ☒ **37 CFR §1.97(b)**
- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
  - within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
  - before the mailing of the first Office action on the merits; **or**
  - before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.
- ☐ **37 CFR §1.97(c)**
- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below.
- ☐ **37 CFR §1.97(d)**

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) **and** a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

A copy of the items on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (\*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. 08/615,369, filed March 14, 1996 and relied upon in this application for an earlier filing date under 35 USC §120.

☐ BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1- A-Q" (nucleotide) and "BLAST Results B-1 - B-Q" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

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A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

☐ given for each listed item

☐ given for only non-English language listed item(s) [Required]

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

In the event that the Office determines a fee to be due where none is specifically authorized in this paper, the U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p).

Respectfully submitted,

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PATENT TRADEMARK OFFICE

FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark Office

Atty Docket No.

P0998D1

Serial No.

09/273,230

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Cleland et al.

Filing Date

18 Mar 1999

Group

1642

## U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	253	4,714,759	22.12.87	Whitaker, Jr.			
	254	4,816,567	28.03.89	Cabilly et al.			
	255	4,861,579	29.08.89	Meyer et al.			
	256	4,946,788	07.08.90	Delespesse			
	257	4,962,035	09.10.90	Leder et al.			
	258	5,091,313	25.02.92	Chang, T.			
	259	5,231,026	27.07.93	Chang, T.			
	260	5,252,467	12.10.93	Chang, T.			
	261	5,254,671	19.10.93	Chang, T.			
	262	5,260,416	09.11.93	Chang, T.			
	263	5,274,075	28.12.93	Chang, T.			
	264	5,292,867	08.03.94	Chang, T.			
	265	5,342,924	30.08.94	Chang, T.			
	266	5,362,643	08.11.94	Chang, T.			
	267	5,420,251	30.05.95	Chang et al.			
	268	5,422,258	06.06.95	Chang, T.			
	269	5,428,133	11.12.91	Chang, T.			
	270	5,654,403	05.08.97	Smith et al.			
	271	5,792,838	11.08.98	Smith et al.			
	272	5,942,210	24.08.99	Ultee et al.			
	273	5,965,709	12.10.99	Presta et al.			
	274	6,080,429	27.06.00	Cleland et al.			
	275	6,267,958	31.07.01	Andya et al.			

## FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No
	276	171,496	19.02.86	EPO			
	277	173,494	05.03.86	EPO			
	278	184,187	11.06.86	EPO			
	279	255,249	03.02.88	EPO			
	280	263,655	13.04.88	EPO			
	281	317,295	24.05.89	EPO			
	282	589,840	30.03.94	EPO			
	283	617,127	28.09.94	EPO			
	284	648,499	19.04.95	EPO			
	285	59-44399	12.03.84	JAPAN (TRANSLATION ATTACHED)			

Examiner

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark OfficeAtty Docket No.  
P0998D1Serial No.  
09/273,230

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant  
Cleland et al.Filing Date  
18 Mar 1999Group  
1642

## FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
	286	WO 86/01533	13.03.86	PCT				
	287	WO 89/04834	01.06.89	PCT				
	288	WO 89/06138	13.07.89	PCT				
	289	WO 91/11456	08.08.91	PCT				
	290	WO 93/04173	04.03.93	PCT				
	291	WO 93/19197	30.09.93	PCT				
	292	WO 95/15977	15.06.95	PCT				
	293	WO 97/04807	13.02.97	PCT				
	294	WO 97/10004	20.03.97	PCT				
	295	WO 97/33616	18.09.97	PCT				
	296	WO 99/01556	14.01.99	PCT				

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

	297	Burton et al., "Lyophilized hyperimmune equine serum as a source of antibodies for neonatal foals" <u>American Journal of Veterinary Research</u> 42(2):308-310 (Feb 1981)
	298	Cleland et al., "Development of Stable Protein Formulations for Microencapsulation in Biodegradable Polymers" <u>Proceed. Intern. Symp. Control. Rel. Bioact. Mater.</u> 22:514-515 (1995)
	299	Natali et al., "Expression of the p185 encoded by HER2 oncogene in normal and transformed human tissues" <u>International Journal of Cancer</u> 45(3):457-461 (Mar 15, 1990)
	300	Nitta et al., "Preliminary trial of specific targeting therapy against malignant glioma" <u>Lancet</u> 335(8686):368-371 (Feb 17, 1990)
	301	Press et al., "Expression of the HER-2/neu proto-oncogene in normal human adult and fetal tissue" <u>Oncogene</u> 5:953-962 (1990)
	302	Ressing et al., "The influence of sucrose, dextran, and hydroxypropyl-/142-cyclodextrin as lyoprotectants for a freeze-dried mouse IgG <sub>2a</sub> monoclonal antibody (MN12)" <u>Pharmaceutical Research</u> 9(2):266-270 (1992)
	303	Valone et al., "Clinical trials of bispecific antibody MDX-210 in women with advanced breast or ovarian cancer that overexpresses HER-2/neu" <u>Journal of Hematotherapy</u> 4(5):471-475 (Oct 1995)

Examiner

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.